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PATIENT INFORMATION

MARINOL® (dronabinol)
Capsules
2.5 mg, 5 mg, 10 mg
for use in the loss of appetite
associated with weight loss in
patients with AIDS.

R_x only



FPO
Data Matrix Code
500013MAR2008

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IMPORTANT

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YOUR DOCTOR HAS PRESCRIBED THIS DRUG FOR YOUR USE ONLY. DO NOT LET ANYONE ELSE USE IT.

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KEEP THIS MEDICINE OUT OF THE REACH OF CHILDREN AND PETS. If a child puts a capsule in his or her mouth or swallows MARINOL® Capsules, take the medicine away from the child and contact a poison control center immediately, or contact a doctor immediately.

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Do not drive a car or operate machinery until you know how MARINOL Capsules affects you. While taking MARINOL Capsules, do not drink alcohol, smoke marijuana, or take other drugs that have an effect on the central nervous system (such as sedatives or hypnotics). Unless advised by your doctor, do not use MARINOL Capsules if you are pregnant or nursing.

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INTRODUCTION

This leaflet provides a summary of information about MARINOL Capsules. Please read it and keep it with your medicines in case you need to look at it again. Ask your doctor, nurse, or pharmacist if you have any questions.

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MARINOL Capsules contains man-made dronabinol (THC). Dronabinol also occurs naturally, and has been extracted from *Cannabis sativa L.* (marijuana).

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PRECAUTIONS

Be sure to tell your doctor if you:

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- have or had heart disease
- have or had cardiac disorders because of occasional hypotension, possible hypertension, syncope, or tachycardia
- have current or a history of drug abuse
- have current or a history of alcohol abuse
- have or had mental health problems (mania, depression, schizophrenia)
- have a history of seizure disorder and/or seizure-like activity
- have allergies to drugs
- are pregnant or nursing, or become pregnant

38 If you become pregnant while taking MARINOL Capsules, stop using it until
39 you have talked to your doctor.

40
41 MARINOL Capsules should be used with caution in children because it has
42 not been studied in children.

43
44 MARINOL Capsules should be used with caution in elderly patients because
45 they may be more sensitive to the neurological, psychoactive, and postural
46 hypotensive effects of the drug.

47
48 MARINOL Capsules can dangerously interact with alcohol and with other
49 drugs that have an effect on the central nervous system (such as Valium,
50 Librium, Xanax, Seconal, Nembutal, or Phenobarbital).

51
52 Do not drive or operate machinery until you are sure how MARINOL Capsules
53 affects you and you are able to perform safely.

54
55 You may experience changes in mood or have other effects when first taking
56 MARINOL Capsules. Be sure that there is a responsible person nearby when you
57 first take MARINOL Capsules or when there is an adjustment in your dose.

58
59 Tell your doctor if you are taking any other prescription or nonprescription
60 medicines.

61
62 Do not smoke marijuana while using MARINOL Capsules. This can cause an
63 overdose.

64
65

INFORMATION ABOUT USING MARINOL CAPSULES

Introduction

66 Eating a nutritionally balanced diet is fundamental for all stages of life. For
67 persons living with Human Immunodeficiency Virus (HIV); it's especially
68 important to ensure an adequate diet to maintain an ideal weight and good
69 nutritional status. There is some indication that optimal nutrition can help
70 maintain the integrity of the immune system, and an adequate diet will allow you
71 to better withstand the diseases associated with an AIDS diagnosis.

72
73

74 Many conditions, frequently interrelated, may cause a loss of appetite.
75 Chewing and swallowing may become difficult or painful, due to inflammation or
76 sores in your mouth and throat.

77

78 You may experience intermittent diarrhea or overall physical discomfort
79 associated with AIDS. Sometimes, shopping for food and preparing adequate
80 meals may drain your energy and desire to eat. Mental depression also may
81 result in a loss of your appetite, or you simply may grow increasingly frustrated
82 with repeated eating problems.

83

84 A loss of appetite may occur at various times during illness associated with
85 HIV infection. It often leads to the selection of an inadequate diet. Because a
86 poor nutrient intake can result in weight loss and malnutrition, it's important to
87 learn to recognize and handle a temporary loss of your appetite.
88

89 Your doctor may prescribe an appetite stimulant such as MARINOL
90 Capsules. MARINOL Capsules should be taken exactly as directed by your
91 doctor, and indicated on the prescription label. You will most likely start therapy
92 by taking one white capsule (2.5 mg) of MARINOL Capsules twice daily, before
93 lunch and supper. Your doctor may adjust your MARINOL Capsules dosage if
94 needed to maximize its effect or to decrease any side effects.
95

96 If you miss a dose, take it as soon as you remember. However, if it is almost
97 time for your next dose, skip the missed dose and go back to your regular dosing
98 schedule. Do not double your dose. MARINOL Capsules must be swallowed
99 whole to work effectively. Do not crush or chew the capsules.
100

101 It is important not to take sedatives, hypnotics, other mind altering
102 substances, or alcohol, while taking MARINOL Capsules without notifying your
103 health care givers (physician, pharmacists and nurses). Do not drive or attempt
104 other activities requiring full alertness while taking MARINOL Capsules. Your
105 doctor will advise when you may resume these activities.
106

107 Your doctor and pharmacist should be made aware of any other prescription
108 medications or over-the-counter products you may be taking, as they could affect
109 the way you respond to MARINOL Capsules.
110

111 Remember to keep this and all other medication out of the reach of children.
112

113 Increasing your appetite is only the first step in improving your nutritional
114 status. How, what, and when you eat are also very important.
115

116 **How to Eat**

117 The purpose of consuming an adequate diet, even at times when you don't feel
118 like eating, is to maintain an ideal weight and good nutritional status. Key to an
119 adequate diet for HIV-infected individuals are foods dense in calories and
120 nutrients. In other words, when you find it difficult to eat, make the most of what
121 you do consume by selecting foods that provide many calories or nutrients in
122 each mouthful.
123

124 Try some of the following ideas to boost your food intake. Keep in mind the
125 foods you previously may have limited in your diet, especially those higher in fat,
126 now can provide a significant source of calories. Enjoy an ice cream sundae
127 frequently.
128

129 Cool or cold foods can dull pain from mouth and throat sores; popsicles may
130 even numb your mouth prior to eating a larger meal. The cooler temperatures
131 also diminish the aroma of unappetizing food.

132
133 Blend one cup of nonfat dry milk powder with one quart of whole milk.
134 Refrigerate and use “double strength” milk for all traditional uses (puddings,
135 cereal, shakes, soups).

136
137 Foods with a softer consistency, such as applesauce, may aid swallowing.
138 Creamed sauces or gravies also moisten food to encourage swallowing.

139
140 Creating an appetizing meal involves more than just food. Try to eat in a
141 pleasant atmosphere – sit in a comfortable chair, use a tablecloth and china,
142 invite a friend to share your meal.

143

144 **What to Eat**

145 Planning ahead is one of the most effective ways to deal with a loss of appetite.
146 Stock up on staple foods, particularly those high in calories and protein, so
147 they’re available when you need them. Include favorite foods on your shopping
148 list. Also consider these protein and nutrient dense foods:

- 149 ● Nonfat dry milk powder
- 150 ● Powdered breakfast drinks
- 151 ● Peanut butter and jelly
- 152 ● Pudding cups
- 153 ● “Trail mix” (dried fruit, nuts, cereals)
- 154 ● Creamed soups
- 155 ● Canned (or frozen) fruit in heavy syrup
- 156 ● Canned tuna, chicken or other sandwich spreads
- 157 ● Boxed macaroni and cheese

158

159 In addition to staples, refrigerated and frozen foods contribute important
160 nutrients to an adequate diet. Several key choices, high in protein and calories,
161 are listed below:

- 162 ● Yogurt
- 163 ● Cheeses
- 164 ● Cold cuts, beef and poultry
- 165 ● Cottage cheese
- 166 ● Ice cream and sherbet
- 167 ● Popsicles or pudding pops
- 168 ● Hard cooked eggs or pasteurized eggs*

169

170 *Raw or undercooked cracked eggs pose danger of *Salmonella*. The
171 compromised immune function of persons with AIDS places them at greater
172 than average risk from *Salmonella* infection.

173

174 Commercial food supplements are also available to boost your caloric and
175 nutrient intake. Offered in a variety of flavors and textures, these products supply
176 a concentrated source of calories and protein. You may want to ask your
177 treatment provider for more information about supplements. You may also
178 request a referral to a registered dietitian who can provide individualized dietary
179 recommendations to you.

180

181 **When to Eat**

182 “Nutritious” meals can be eaten three times a day, but frequent, small snacks or
183 meals can help you consume the calories and protein you need without feeling
184 full from a large meal. Eat when you feel hungry, using modern technology,
185 including your microwave, to quickly prepare a nutritious snack or meal.

186

187 **Storage Instructions**

188 The best place to store MARINOL Capsules is in a cool place (46-59°F; 8-15°C)
189 or in the refrigerator. Be careful that the capsules don’t freeze. Heat or moisture
190 may cause your MARINOL Capsules to break down or stick together, so keep
191 your medicine away from heat and direct light, and potentially damp places like in
192 the bathroom or near the kitchen sink.

193

194 **If You Are Taking Medicines**

195 MARINOL Capsules use may change the effect of other medicines. It is
196 important to tell your doctor about all the medicines you are taking including all
197 non-prescription medication.

198

199 **What to Watch For (Adverse Effects)**

200 You should not smoke marijuana while using MARINOL Capsules. It is possible
201 to get too much dronabinol (an overdose), especially if you use MARINOL
202 Capsules and smoke marijuana at the same time. Signs of a mild overdose
203 would include drowsiness, euphoria, heightened sensory awareness, altered time
204 perception, red eyes, dry mouth and rapid heart rate (tachycardia). Moderate
205 overdosage would produce memory problems, depersonalization, mood
206 alteration, urinary retention, and constipation. Severe overdosage would lead to
207 decreased motor coordination, lethargy, slurred speech, and dizziness when
208 standing up too fast (postural hypotension).

209

210 An overdose might cause you to faint.

211

212 **If You Have Problems in the First Few Days**

213 When you first use MARINOL Capsules your body is more sensitive and you may
214 experience dizziness, confusion, sleepiness, or a high feeling. These symptoms
215 usually go away in 1 to 3 days with continued dosage. If these symptoms are
216 troublesome or persist, notify your doctor at once. Your doctor may then reduce
217 the dose to one capsule before supper, or later in the evening, or even at
218 bedtime.

219

220 **What to Do When Problems Occur**
221 **IF YOU NOTICE ANY WORRISOME SYMPTOMS OR PROBLEMS, STOP THE**
222 **MARINOL CAPSULES AND CALL YOUR DOCTOR AT ONCE.**

223

224

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227 High Point, NC 27265

228

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231 Marietta, GA 30062

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